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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,262

07/09/2007

Wolfgang Hillen

06-40247US

1254

7066

7590

11/02/2009

REED SMITH LLP

2500 ONE LIBERTY PLACE

1650 MARKET STREET

PHILADELPHIA, PA 19103

EXAMINER

QIAN, CELINE X

ART UNIT

PAPER NUMBER

1636

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/594,262	<b>Applicant(s)</b> HILLEN ET AL.	
	<b>Examiner</b> CELINE X. QIAN	<b>Art Unit</b> 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

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### DETAILED ACTION

Claims 1-24 are pending in the application.

#### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, drawn to a method for monitoring the expression level of a gene in a host cell by modulating the activity of a regulatory biomolecule, comprising the steps of: transforming a cell expressing a regulatory biomolecule with a nucleic acid comprising an open reading frame encoding an interaction partner of said biomolecule in expressible form, wherein said regulatory biomolecule is either a nucleic acid binding molecule or an allosterically controlled ribonucleic acid molecule; and the interaction partner of the biomolecule is a tagged polypeptide, assessing the expression level of the gene.

Group II, claim(s) 9, drawn to a method of producing and/selecting a compound capable of modulating the activity of a nucleic acid binding protein by conducting a selection of compounds with the nucleic acid binding target protein, removing unspecifically bound compounds; detecting specific binding of the compound, expressing the nucleic acid binding protein and providing in trans the coding sequence of an indicator gene under the control of the target sequence of the nucleic acid binding protein; adding a candidate compound to the cell; determine the amount of activity of the indicator protein, selecting compounds capable of modulating the activity of the nucleic acid binding protein.

Groups III-XX, claims 10, 12-21, 23 and 24, drawn to a nucleic acid molecule encoding a polypeptide sequence as set forth in SEQ ID NO: 1-17, respectively (groups III-XX) and a complementary strand hybridizes to said molecule, wherein said nucleic acid molecule encodes an interaction partner which is capable of modulating the activity of a nucleic acid binding protein, a vector comprising said nucleic acid, a host cell containing said nucleic acid molecule, a kit comprising the nucleic acid, the vector or the host cell or ensemble of host cells, and use of the nucleic acid.

Group XXI, claims 11, 23 and 24, drawn to polypeptide encoded by a nucleic acid, a kit comprising said polypeptide and use of said polypeptide.

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Group XXII, claim 22, drawn to a non-human animal comprising a host cell that comprises the nucleic acid encoding a polypeptide that binds nucleic acid sequence.

PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-XXII do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The “special technical feature” of Group I is a regulatory biomolecule being a nucleic acid binding molecule or an allosterically controlled ribonucleic acid molecule, and a interaction partner encoded by a nucleic acid molecule, expressed both in a cell. This special technical feature is shown by Toby et al. (see IDS), which teach yeast interaction trap, yeast two hybrid system for detecting protein-protein interaction. The yeast cells are transformed with a regulatory molecule which is a fusion of a DNA binding domain and a protein (bait), and a binding partner which is a fusion of activation domain and a protein that interacts with the regulatory molecule (prey) (see Figure 1, for example). As such, this special technical feature lack novelty or inventive step over the disclosed yeast two hybrid system, and does not make a contribution over the prior art. As such, this technical feature cannot link the invention as a whole to form a single general inventive concept under PCT Rule 13.1.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not

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distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be

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amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELINE X. QIAN whose telephone number is (571)272-0777. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Celine X Qian /  
Primary Examiner, Art Unit 1636